



Poultry Council

PennAg Industries Association

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20855

Response to Docket 00N-1571

The FDA is proposing to withdraw its approval of the use of an important fluoroquinolone type antibiotic, Baytril, for poultry.

The reason given for this proposed action is that the use of Baytril, which is closely related to a similar type of antibiotic used in people (ciprofloxacin – also a fluoroquinolone) appears to have resulted in the development of resistant *Campylobacter* bacteria in poultry. This *Campylobacter* bacteria, which can be a human pathogen, can then be transferred to people via food and result in the development of resistant *Campylobacter* infection in people. Most cases of *Campylobacter* infection cause a transient gastroenteric illness.

Our Pennsylvania poultry industry developed and operates the most intensive production food safety program in the country, the PA Egg Quality Assurance Program (PEQAP). We would support such FDA action if we felt that unreasonable risk was being created for people. But at this time, we believe the proposed fluoroquinolone withdrawal action, given the incomplete and often conflicting information available, may not be in the best interest of public health or the poultry industry.

We believe that the appropriate action is to delay any final decision until the FDA has had an opportunity to complete the evaluation and decision process as was initially outlined by that agency. We also believe that industry needs to be presented with any new information that may be available and also have the opportunity to present any information and/or questions it believes may be relevant.

Our concerns that this withdrawal action may be premature and may not be in the best interests of the public or industry are based on the following:

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- 1) We recognize that in 1998-99 approximately 13-17% of the human *Campylobacter* isolates and about 9% of the poultry isolates were reported to be resistant to the fluoroquinolone class of antibiotics.
- 2) We also recognize that consumption of chicken is believed to be an important source of foodborne *Campylobacter* infection. On the other hand food scientists and food safety experts agree that *Campylobacter* infection from food will only occur where food is inadequately cooked or cross-contaminated – i.e. a responsibility of the food preparer.
- 3) We are concerned that there are clearly other potential ways in which bacteria such as *Campylobacter* may be exposed to antibiotics and become resistant. Today there is a significant question as to what % of antibiotic resistance may arise from improper use in human medicine (as overprescribing, poor patient compliance, etc.) and use in animals. One estimate of overuse in people is that there are 60 million antibiotic prescriptions per year given to children for childhood viral problems that don't respond to antibiotics.
- 4) Ciprofloxacin has been used in people since 1986 and although the statement has been made "that resistance to the fluoroquinolones did not increase in *Campylobacter* bacteria above a low level until 1996 or 1997, or soon after the approval of fluoroquinolones in poultry" we would submit that only in the past several years has there been more concern and this a much more extensive and routine testing of *Campylobacter* (and several other potential pathogens) for antibiotic resistance. This extensive testing since 1997 has been done through the National Antibiotic Resistance Monitoring Study (NARMS).
- 5) Baytril is used only upon prescription of a licensed veterinarian that has an established veterinary-client relationship with the producer. Because of its cost and the concern about development of resistance, it is only used where other therapies would be inadequate to prevent significant mortality and morbidity in broilers or turkeys due to *E coli* or *Pasteurella*. Although no good studies are available and it would be difficult to determine, effective treatment with Baytril could be reducing other significant public health problems from such bacteria as *E coli* and *Salmonella* on otherwise inadequately treated birds. Increased flock losses also eventually will translate into higher food costs – a significant problem for the elderly, families, and others on lower and fixed incomes.
- 6) Because of the above we believe an exhaustive and complete cost:benefit analysis which includes the above as well as other factors should precede any final determination of appropriate action to be taken.
- 7) There is an increasing recognition of the potential concerns about use of antibiotics in animals and the veterinary profession and industry are increasingly addressing these concerns by education and utilization of "Best Management Practices", the judicious use of antibiotics, and use of alternative therapies. Just two examples of this are the recent development of a 13 page recommended "Judicious Use of Antimicrobials for Poultry Veterinarians" and the development of an on-line therapeutically based antimicrobial use database called the "Veterinary Antimicrobial Decision Support System" which will provide easily accessible information to help veterinarians make wise therapeutic


decisions. Both of these initiatives are sponsored by the American Veterinary Medical Association.

8) Public policy and any regulatory action should be based on sound science and complete cost:benefit analysis. Antibiotics are important both to human health and when necessary to aid in the production of healthy animals. We believe the current proposal requires more extensive evaluation before a final decision is made. To not do so could establish a dangerous precedent for future actions – actions which if not based on sound science and a complete risk:benefit analysis could be detrimental to both public health and the production industries. We request that you support delaying a final decision on this fluoroquinolone issue by FDA until the initially proposed and complete evaluation is final.


Finally, our Pennsylvania producers and the veterinarians that serve them do have as a priority, the overall welfare of the public for whom we produce food. We will support any decision that is subsequently based on the considerations presented above.

Thank you for your consideration and support.

Sincerely,



James A. Shirk
Assistant Vice President

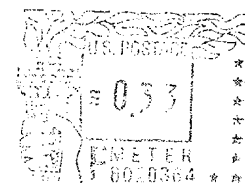


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